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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,623	12/21/2001	Ronald V. Swanson	09010-105004	9858

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MORRISON & FOERSTER LLP  
3811 VALLEY CENTRE DRIVE  
SUITE 500  
SAN DIEGO, CA 92130-2332

EXAMINER

MINNIFIELD, NITA M

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/034,623

Applicant(s)

SWANSON ET AL.

Examiner

N. M. Minnifield

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 5-10 is/are pending in the application.
- 4a) Of the above claim(s) 5, 6 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 7-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 5, 6 and 10 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 3 sheets
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9-5-02; 9-6-02 4 sheets total
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

1. Applicant's election of Group I, claims 1, 2 and elected SEQ ID NO: 6, in the reply filed on October 1, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Applicants' amendment filed October 1, 2004 is acknowledged and has been entered. Claims 3 and 4 have been canceled. Claims 1 and 2 have been amended. New claims 5-10 have been added. Claims 1, 2 and 5-10 are now pending in the present application. It is noted that claims 7-9 are directed to the elected invention of an antibody. Claims 1, 2 and 7-9 will be examined in the pending application.
3. Claims 5, 6 and 10 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 1, 2004.
4. Applicants have requested that after the elected product claims have been found to be allowable, that all process (methods) claims which depend from or otherwise include all of the limitations of the allowed product claims can be rejoined. MPEP 821.04; pg 800-63, 8<sup>th</sup> Edition, August 2001; In re Ochiai, 37 USPQ2d 1127 (Fed. Cir. 1995); In re Brouwer, 37 USPQ2d 1663 (fed. Cir. 1995); 1184 OG 86, 3/26/96.

5. Claims 1, 2 and 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicant regards as the invention. The claims are vague and indefinite in the recitation of "capable of". It has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

6. The disclosure is objected to because of the following informalities: p. 8, l. 25 "i", what does Applicant intend? Appropriate correction is required.

7. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

8. The use of trademarks has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

9. Claims 2 and 7-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated antibody that binds to a

polypeptide comprising SEQ ID NO: 6, does not reasonably provide enablement for an isolated antibody that binds to a polypeptide comprising at least 10, 15, 20, 25, 30, 35, 40, 50, 75 or 100 consecutive amino acids of SEQ ID NO: 6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It is noted that the specification sets forth guidance with regard to making polyclonal or monoclonal antibodies in general (see pp. 35-36 for example). Since the polypeptide, SEQ ID NO: 6, has been isolated or made recombinantly, the actual process of making such an antibody that binds to a polypeptide comprising SEQ ID NO: 6 would be within the skill level of one of skill in the art. However, claim 2 recites that the polypeptide comprises fragments of the polypeptide of SEQ ID NO: 6, at least 10, 15, 20, 25, 30, 35, 40, 50, 75 or 100 consecutive amino acids of SEQ ID NO: 6. Determining which fragments will still specifically bind to the claimed antibody is not set forth in the specification nor is there any guidance provided to one of skill in the art regarding how to prepare or which of the many fragments possible from a polypeptide comprising at least 269 amino acids. The scope of the claims is not commensurate with the enablement provided by the specification with regard to the extremely large number of possible fragments of the polypeptide of SEQ ID NO: 6. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which fragments of the polypeptide will still be able to bind to the antibody is difficult. The specification does not set forth any of the epitopes of the polypeptide comprising SEQ ID NO: 6. The specification does not provide any evidence that the polypeptide of SEQ ID NO: 6 has any function or other biological properties.

Schleper et al (1998, Medline) indicates that the polypeptide comprising SEQ ID NO: 6 is similar to eukaryotic histone H1 DNA binding protein, although the specification does not set forth or assign any function to the polypeptide comprising SEQ ID NO: 6.

The specification does not support the broad scope of the claims, which encompass all modifications and fragments because the specification does not disclose the following:

- the general tolerance to modification and extent of such tolerance;
- specific positions and regions of the sequences) which can be predictably modified and which regions are critical;
- what fragments, if any, can be made which retain the biological activity of the intact protein; and
- the specification provides essentially no guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed fragment or part sequence of the protein in a manner reasonably correlated with the scope of the claims broadly including any number of fragments (i.e. at least 10, 15, 20, 25, 30, 35, 40, 50, 75 or 100 consecutive amino acids) and active part sequence (i.e. fragments of any size). The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, the changes which can be made in the proteins structure and still maintain activity is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *Amgen. Inc. v. Chugai Pharmaceutical Co. Ltd.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991) at 18

USPQ2d 1026-1027 and Ex parte Forman, 230 U.S.P.Q. 546 (Bd. Pat. App. & Int. 1986).

Houghten et al. teach that changes/modifications (addition, substitution, deletion or inversion) of one or more amino acids in a polypeptide will alter antigenic determinants and therefore effect antibody production (p. 21) as well as antibody binding. Houghten et al. also teach that "... combined effects of multiple changes in an antigenic determinant could result in a loss of [immunological] protection." and "A protein having multiple antigenic sites, multiple point mutations, or accumulated point mutations at key residues could create a new antigen that is precipitously or progressively unrecognizable by any of the antibodies..." (p. 24). Houghten et al. teach that point mutations at one key antigen residue could eliminate the ability of an antibody to recognize this altered antigen (p. 24).

In view of all of the above it is determine that it would require undue experimentation of one of skill in the art to make and use the invention commensurate in scope with the claimed subject matter of an antibody that specifically binds to a fragment of the polypeptide comprising SEQ ID NO: 6.

10. No claims are allowed.

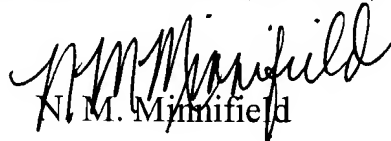
11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is

571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "N. M. Minnifield".

N. M. Minnifield  
Primary Examiner

Art Unit 1645

NMM

December 16, 2004